

REMARKS

Claims 1 – 19 are pending and claims 21 and 22 are withdrawn. Claims 1 – 5 and 8 – 15 have been amended. Claim 22 has been added. Claims 6, 7, and 16 – 19 have been canceled. Upon entry of this amendment, claims 1 – 5, 8 – 15, and 22 will be pending.

No new matter has been added. Independent claims 1– 5 have been amended to incorporate the limitation of original claim 7. Independent claim 8 has been amended to incorporate the limitation of original claim 18. Independent claim 9 has been amended to incorporate the limitation of original claim 19. Support for new claim 22 can be found, for example, at page 10, lines 8 – 18.

Objection to the Specification

The Abstract of the disclosure has been objected to because it allegedly contains legalese. Applicants have amended the Abstract to recite “include” rather than “comprise.” Withdrawal of the objection is therefore requested.

Claim rejections - 35 U.S.C. §112, second paragraph

Claims 1, 7, and 19 have been rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Specifically, the Examiner has contended that there is insufficient antecedent basis for the limitations “a DNA,” “a step of growing,” and “a chlorella virus.”

Applicants traverse the rejections because the limitations “a DNA,” “a step of growing,” and “a chlorella virus” do not refer to any earlier recitation of limitation, and therefore do not require an antecedent basis. Applicants have amended claims 1 and 2 to recite “a step of growing a transformant obtained by transformation of step (1).” Accordingly, withdrawal of the rejections is requested.

Claim rejections - 35 U.S.C. §101

Claims 9 – 13, 15, and 17, and 19 have been rejected under 35 U.S.C. §101 as allegedly being directed to non-statutory subject matter. Specifically, the Examiner has contended that the claim encompasses progeny that lack the transgene.

Applicants traverse the rejections. However, to advance prosecution, Applicants have amended independent claim 9 to clarify that the claimed plants and the progeny, organ, and tissue thereof have the ability of producing hyaluronic acid. Because naturally-occurring plant and the progeny, organ, and tissue thereof do not have the ability of producing hyaluronic acid, the claimed subject matter could not occur in nature. Accordingly, withdrawal of the rejections is requested.

Claim rejections - 35 U.S.C. §112, first paragraph

Claims 1 – 19 have been rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement, and as allegedly being non-enabling for any hyaluronic acid synthase (HAS) gene from any species or any sequence variants thereof.

Applicants traverse the rejections. However, to advance prosecution, Applicants have amended independent claims 1 – 4, 8, 9, 14, and 15 to recite “wherein the hyaluronic acid synthase is derived from chlorella virus.” As the Examiner has admitted, Applicants describes HAS from chlorella virus, and the specification is enabling for the chlorella HAS gene. Office Action, pages 6 and 9. Accordingly, withdrawal of the rejections is requested.

Claim rejections - 35 U.S.C. §103

Claims 1 – 19 have been rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Smeekens et al. (US6,147,280) in view of DeAngelis et al. (Hyaluronan Synthase of Chlorella Virus PBCV-1, *Science* 1997: Vol. 278., pp. 1800 – 1803) and further in light of Akasaka (US4,801,539) and Mattes et al. (US5,985,668). Applicants traverse the rejections.

To establish a *prima facie* case of obviousness, a reference must (1) teach all the present claim limitations; (2) suggest to or provide motivation for one of ordinary skill in the art to make the claimed invention; and (3) provide one of ordinary skill with a reasonable expectation of success in so making. *See In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991) (*citing In re Dow Chemical Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988)). “Both the suggestion and the reasonable expectation of success must be found in the prior art reference, not in the applicant’s disclosure.” *In re Vaeck* at 493.

As the Examiner has admitted, none of the references alone teach the composition as claimed. Applicants submit that there is a lack of motivation to combine the references. Smeekens is directed to a method of producing oligosaccharides, which are to be used as sugar substitutes (see col. 1, lines 26 – 27). According to Smeekens, oligosaccharides are molecules which consist of two or more monosaccharides such as fructose and/or glucose (see col. 1, lines 27 – 29), desired oligosaccharides have a chain length of 2 to about 7 (see col. 2, lines 12 – 13), and oligosaccharides with too high a chain length have little sweetening power (see col. 2, lines 22 – 24). Therefore, Smeekens teaches away from a polysaccharide with a high degree of polymerization (see also col. 2, lines 58 – 63). On the other hand, DeAngelis discloses hyaluronan synthases that produce hyaluronic acid, which, according to DeAngelis, is a linear polysaccharide composed of 1000 to 10000 monosaccharides (see page 1800, first paragraph). Such a large polysaccharide cannot belong to the oligosaccharides family taught or suggested by Smeekens, and cannot provide the sweetening power sought by Smeekens. As a result, one of ordinary skill in the art would not have been motivated to combine Smeekens and DeAngelis.

Further, Applicants submit that there is a lack of reasonable expectation of success. Smeekens discloses fructosyltransferases that convert sucrose into oligosaccharides. DeAngelis discloses hyaluronic acid synthases that produce hyaluronic acid. The fructosyltransferases disclosed by Smeekens and the hyaluronic acid synthases disclosed by DeAngelis are different in at least the following aspects:

- (1) Fructosyltransferases are a naturally-occurring in plants (see Smeekens, col. 4, lines 45 – 52), while hyaluronic acid synthases are not (See Specification, page 4, lines 28 – 30);
- (2) Fructosyltransferases transfer fructose units from sucrose to fructan acceptor molecule (see col. 4, lines 1 – 3), while hyaluronic acid synthases polymerize hyaluronic acid using activated uridine diphosphate-sugar nucleotides as substrates (See DeAngelis, page 4, lines 28 – 30);
- (3) The hyaluronic acids produced hyaluronic acid synthases and the oligosaccharides produced by fructosyltransferases are different in terms of sugar units, molecular weight, and degree of polymerization, etc.

As such, one of ordinary skill in the art would not have had a reasonable expectation of success by combining Smeekens and DeAngelis.

The deficiency of Smeekens and DeAngelis is not cured by Akasaka or Mattes because none of them provides the required motivation to combine and reasonable expectation of success.

Therefore, for at least the reasons stated above, a *prima facie* case of obviousness has not been established. Withdrawal of the rejections is requested.

CONCLUSION

The claims are believed to be allowable.


The Examiner is invited to contact the undersigned at (202) 220-4200 to discuss any matter concerning this application.

In the event that the filing of this paper is deemed not timely, Applicants petition for an appropriate extension of time. The Office is authorized to charge any additional fees or credit any overpayments to deposit account 11-0600 of Kenyon & Kenyon LLP.

Respectfully submitted,
KENYON & KENYON LLP

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By:



Michelle H.W. Shen
Reg. No: 48,823

1500 K Street, N.W.
Washington, D.C. 20005
Telephone: (202) 220-4200
Facsimile: (202) 220-4201
Customer No. 23838